

REMARKS

The Office action dated September 13, 2007 is acknowledged. Claims 1-44 are pending in the instant application. According to the Office action, claims 13-24 and 34-44 have been withdrawn and claims 1-12 and 24-33 have been rejected. Claims 1 and 13 have been amended to more clearly define the present invention, support for which may be found throughout the specification, such as at paragraphs [000012], [000023], [000028] and [000049]. Reconsideration is respectfully requested in light of the amendments being made hereby and the arguments made herein. No new matter has been added.

Election/Restriction

The Examiner acknowledges in the Office action the election with traverse of Group 1, claims 1-12 and 25-33 which had been set forth in the previous reply and notes that the traversal on the ground(s) that the cited reference of Bessette, et al. does not teach the technical feature of the current invention has been found persuasive. However, the Examiner states that since Group I does not require the existence of 0.1-1% Al-acetylacetonate (claim 22), 20-35% of anhydrous glycerol and 15-25% propylene glycol (claim 23) in Group II, there is no special technical feature in the application. Accordingly, the Examiner concludes that the groups are not so linked as to form a single general concept under PCT Rule 13.1 and has thus made the election final. Therefore, the Examiner has withdrawn claims 13-22 and 34-44 from further consideration as being drawn to non-elected inventions. The Applicants respectfully object to the instant restriction requirement, with traverse and withdrawal of this objection is therefore respectfully requested.

Rejection of Claims 1-12 and 24-33 under 35 U.S.C. 103(a)

Claims 1-3, 7-11, 25-27 and 31-33 have been rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,090,403 (Block, et al.). The Examiner argues that Block, et al. teaches a skin patch for the relief of colds (claim 1), including an underlying layer of non-irritating medical grade pressure-sensitive adhesive, and a foraminous upper carrier layer to which the decongestant-containing ointment is applied (col. 5, lines 4-10). The Examiner further states that the patch is capable of allowing moisture from the skin to diffuse outwardly and escape through the upper surface of the patch (col. 2, lines 52-60). Still further, the Examiner states that the skin patch includes a thickener comprising a natural or synthetic gel-forming polymer selected from the group consisting of gum karaya, carboxymethyl cellulose, polyacrylamide and polyacrylic acid, as well as a humectant comprising a polyhydric alcohol and the antitussive is camphor or menthol. The Examiner confirms that Block, et al. do not teach the specific claimed amounts of water content of the matrix, hydrophile polymer, essential oil, pressure-sensitive adhesive polymer and adjuvants. The Examiner thus concludes that it would have been obvious to use the invention of Block, et al. to arrive at the present invention while noting that the specific amounts of the aforementioned items would be obtained by one skilled in the art.

Claims 1-11, 25-29 and 31-33 have been rejected as being unpatentable over the combination of Block, et al. and U.S. Patent Application Publication No. 2003/0167556 (Kelley). The Examiner essentially argues that Block, et al. teach the present invention except for the adsorbent cyclodextrin, emulsifier sodium lauryl sulfate or any claimed amounts of the water content of the matrix, the claimed adsorbent, the emulsifying

substance, the detachable protective layer, the hydrophile polymer, essential oil, pressure-sensitive adhesive polymer, adjuvants, emulsifying substance and moisturizers. In addition, the Examiner states that Kelley teaches the missing features of Block, et al. and concludes that it would have been obvious to combine the teachings to arrive at the presently claimed invention.

Claims 1-11 and 25-33 have been rejected as being unpatentable over the combination of Block, et al., Kelley and U.S. Patent No. 5,780,047 (Kamiya, et al.). In this instance, the Examiner repeats the previous rationale for Block, et al., namely, that it teaches the present invention except for adsorbent cyclodextrin, emulsifier sodium lauryl sulfate or any claimed amounts of the water content of the matrix, the claimed adsorbent, the emulsifying substance, the detachable protective layer, the hydrophile polymer, essential oil, pressure-sensitive adhesive polymer, adjuvants, emulsifying substance and moisturizers. In addition, the Examiner states that Kelley teaches the missing features of Block, et al. and that Kamiya, et al. teach that the patch is applied on a human skin and exerts medicinal effects on painful stiff neck and shoulder, as well as that the patch may contain essential oils and perfumed oils, such as pine oil. The Examiner concludes that it would have been obvious to combine the teachings of these references to arrive at the presently claimed invention.

Claims 1-12 and 25-33 have been rejected as being unpatentable over the combination of Block, et al., Kelley, Kamiya, et al. and U.S. Patent No. 5,527,536 (Merkle, et al.). Here, the Examiner again repeats the previous rationale for Block, et al., Kelley and Kamiya, et al. In addition, the Examiner argues that Merkle, et al. teach a patch for controlled release of readily available volatile active substances to the skin,

where the patch comprises a back layer, and a water-insoluble adhesive film bonded to the back layer, plus a detachable film covering the adhesive film (page 12). The Examiner concludes that it would have been obvious to combine the teachings of these references to arrive at the presently claimed invention.

The Applicants respectfully submit that to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference (or references when combined) must teach or suggest all of the claim limitation. The Applicants respectfully submit that one skilled in the art would have no suggestion or motivation to combine the aforementioned references in order to arrive at the present invention. Additionally, even if one skilled in the art were to consider Block, et al. alone, or in combination with the cited secondary references, each and every limitation of the present invention would not be disclosed, nor would there be a reasonable expectation of success if the aforementioned references were to be considered.

The Applicants respectfully disagree with the Examiner's conclusion set forth in the Office action. Both the disclosure of the present specification and that of Block, et al. concern medicinal patches for treating colds by releasing vaporizable decongestants. However, the medicinal patch of the present invention and the skin patch set forth in Block, et al. are fundamentally different in their respective approaches of how to support drug-loading and release of the decongestant, as will be explained below.

Block, et al. teach a skin patch comprising a flexible foraminous carrier having a huge number of minute foramina to provide a large surface for facilitating vaporization of

the inhalable decongestant which is distributed over the surface. The skin patch shall be adhesively bonded to the body. To this end, the foraminous center is provided with a pressure-sensitive adhesive layer that may render the patch occlusive.

The inhalable decongestant may be dispersed in a vehicle to form an ointment and the vehicle may be either hydrophilic or hydrophobic. The hydrophilic vehicle includes a thickener comprising a water-dispersible or water-swellaable natural or synthetic polymer, water and a humectant. The water-dispersible or water-swellaable polymer may, for instance, be karaya gum, carboxymethyl cellulose or carboxypropyl cellulose. The hydrophobic vehicle comprises a pressure-sensitive adhesive matrix, such as natural or synthetic rubbers, acrylic adhesives or silicone adhesives. Moreover, the foraminous carrier may be impregnated with such an ointment, thereby spreading the ointment over the large surface of the carrier.

It is submitted that the skin patch according to Block, et al. does not have a backing layer (as in the case of the present invention and as set forth in the present claims), as a backing layer and foraminous carrier are clearly distinct elements with respect to their structure and function within the different patches. The backing layer of the medicinal skin patch of the present invention is clearly not a carrier for the decongestive inhalant, but rather prevents soiling of the user's clothing. The medicinal skin patch of the present invention contains the inhalable essential oil in a polymer matrix, as is evidence from its manufacturing process, is not spread over a large surface of a foraminous carrier. In fact, a patch of the present invention does not have a foraminous carrier but rather the matrix is a compact, non-foraminous structural element of the medical skin patch of the present invention.

The polymer matrix of the medical skin patch of the present invention comprises at least one essential oil (e.g., an inhalable decongestant, as recited in the present claims), at least one hydrophile polymer (e.g., gums) and at least one pressure-sensitive adhesive polymer. In addition, the polymer matrix of the medical skin patch of the present invention further comprises at least one substance having an absorbent effect and/or at least one substance having an emulsifying effect.

With respect to the hydrophile polymer and the pressure-sensitive polymer, both being present in the polymer matrix, it is respectfully submitted that Block, et al. teach that the ointment either contains a hydrophilic vehicle or a pressure-sensitive adhesive (i.e., the hydrophobic vehicle). Block, et al. fail to explicitly teach or disclose that the ointment may comprise both a hydrophilic and a hydrophobic vehicle.

It is further respectfully submitted that it should be realized that the water content of the matrix of the medicinal skin patch pursuant to the present invention is less than 5% by weight despite the presence of the hydrophile polymer(s). To the contrary, Block, et al. teach that the hydrophilic ointment contains water (col. 3, line 15), whereas the medicinal skin patch of the present invention enables absorption of a large amount of moisture with losing its structural integrity in the absence of any carrier.

Therefore, the Applicants respectfully submit that Block, et al. fail to teach or disclose any information to one skilled in the art that would motivate him or her to amend the skin patch according to Block, et al. in that the structural differences to the patch of the present invention would be overcome, in particular if the conceptual differences between the respective patches are considered. Therefore, the Applicants submit that the Block, et al. reference fails to render the presently claimed invention obvious, either

alone or in combination with the remaining cited prior art.

Turning now to Kelley, the Applicants submit that the reference fails to make up for the aforementioned deficiencies of Block, et al. In particular, the reference pertains to transdermal therapeutic patches for percutaneous administration of anti-aging compounds. Thus, the reference pertains to a substantially different medicinal field than the invention discussed in Block, et al. (more specifically, the reference concerns a cosmetic application) and concerns very different purposes. In contrast to a transdermal administration of an active ingredient, the medicinal skin patches of the present invention and Block, et al. concern evaporation of volatile decongestants from the patch, and the subsequent inhalation of the evaporated volatile decongestants from the patch. Inhalation and transdermal administration are different routes of drug delivery which rely on very different mechanical properties, and therefore cannot be compared with each other. Therefore, it is submitted that one skilled in the art who is concerned with realizing administration forms for inhalation therapy in the form of a patch would not have referred to prior art such as Kelley, which discloses transdermal delivery.

In addition, it is submitted that Kelley teaches that an emulsifying agent enhances topical absorption of certain drugs. However, since the Block, et al. reference does not pertain to transdermal drug delivery, one skilled in the art cannot infer any necessity (i.e., there would be no motivation) as to why the emulsifying agent of Kelley should be incorporated into an inhalation therapy patch in accordance with Block, et al. The Applicants respectfully submit that it is clearly not *prima facie* obvious to combine the teachings of Kelley with Block, et al. in order to arrive at the presently claimed invention since there would be no motivation to do so. As such, it would not be obvious for one

skilled in the art to incorporate an emulsifying agent into a hydrophile pressure-sensitive adhesive polymer matrix comprising at least one essential oil, at least one hydrophile polymer and at least one pressure-sensitive adhesive polymer for improving stability and manufacturability of a patch for inhalation therapy. Still further, even if one skilled in the art were to combine said teachings, each and every limitation of the present claims would not be disclosed.

Turning now to Merkle, et al. '536 and Kamiya, et al. '047, both references fail to make up for the numerous deficiencies of both Block, et al, and Kelley. Therefore, even if one skilled in the art were to combine the teachings of said prior art, each and every limitation of the presently claimed invention would not be met.

It is therefore respectfully submitted that the present invention defined in the present claims is patentably distinguishable over the combination of prior art teachings under 35 U.S.C. 103(a). Based on the aforementioned differences, each and every element of the present invention recited in the present claims are not set forth in the Block, et al., alone or in combination with any of the cited secondary and/or tertiary references. Moreover, one skilled in the art would not be motivated to combine said references or to modify Block, et al. to arrive at the presently claimed invention. Therefore, the Applicants respectfully request that this rejection be withdrawn.

Conclusion

For the foregoing reasons, it is believed that the present application, as amended, is in condition for allowance, and such action is earnestly solicited. Based on the foregoing arguments, amendments to the claims and deficiencies of the prior art references, the Applicant strongly urges that the obviousness-type rejection and

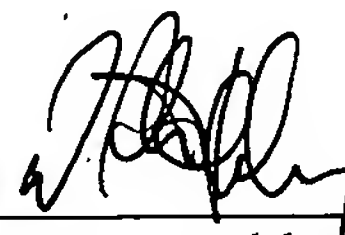
anticipation rejection be withdrawn. The Examiner is invited to call the undersigned if there are any remaining issues to be discussed which could expedite the prosecution of the present application.

Respectfully submitted,

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